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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,971	09/24/2003	Dan-Ning Hu	A35422 073513.0102	7023

21003 7590 03/08/2005

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EXAMINER

NGUYEN, QUANG

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

4/C

Office Action Summary

Application No.

10/670,971

Applicant(s)

HU ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 and 11-18 is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 11/23/04 has been entered.

Amended claims 1-9 and 11-19 are pending in the present application.

Response to Amendment

The rejections under 35 U.S.C. 102(b) as being anticipated by Yanase et al. (US 5,916,809), Hu et al. (Exp. Eye Res. 71:217-224, 2000) are withdrawn in light of Applicants' amendment.

The rejection under 35 U.S.C. 102(b) as being anticipated by Swope et al. (Experimental Cell Research 217:453-459, 1995) is partially withdrawn in light of Applicants' amendment.

The rejection under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (J. Dermatology 27:434-439, 2000) in view of Swope et al. (Experimental Cell Research 217:453-459, 1995) is withdrawn in light of Applicants' amendment.

The rejection under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (J. Dermatology 27:434-439, 2000) in view of Swope et al. (Experimental Cell Research 217:453-459, 1995) and further in view of Hu et al. (Exp. Cell Res. 217:453-459, 1995) is withdrawn in light of Applicants' amendment, and the 1.132 Declaration of Dan-Ning Hu filed on 11/23/04.

The rejection under 35 U.S.C. 103(a) as being unpatentable over Yanase et al. (US 5,916,809) in view of Hu et al. (Pigment Cell Res. 13 Suppl 8:81-86, 2000) is

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withdrawn in light of Applicants' amendment, and the 1.132 Declaration of Dan-Ning Hu filed on 11/23/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Swope et al. (Experimental Cell Research 217:453-459, 1995) for the same reasons already set forth in the Office action mailed on 6/16/2004 (pages 3-4).

Response to Arguments

Applicant's arguments related to the above rejection in the Amendment filed on 11/23/04 (pages 6-7) have been fully considered, but they are not found persuasive.

Applicants mainly argue that the presently claimed composition is distinct from the composition of Swope, and that Swope fails to teach each and every limitation of the claim as amended.

Please note that the amended claim 19 is interpreted by the Examiner as a product-by-process claim, for this instance epidermal melanocytes which are being cultured or prepared in the recited composition. The epidermal melanocytes of Swope are indistinguishable from the epidermal melanocytes of the present invention.

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Additionally, please, also note that where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*. Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the **PTO's inability to manufacture products or to obtain and compare prior art products**. In *re Best*, *Bolton*, and *Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Accordingly, amended claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Swope et al. (*Experimental Cell Research* 217:453-459, 1995) for the same reasons already set forth in the Office action mailed on 6/16/2004 (pages 3-4).

Conclusions

Claims 1-9 and 11-18 are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

Quang Nguyen, Ph.D.


DAVID GUZO
PRIMARY EXAMINER